



DEPARTMENT OF HEALTH AND HUMAN SERVICES

945171

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

January 22, 2004

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-16

Luis B. Dominguez, President
Dominguez Family Enterprises, Inc.
2885 Van Horn Drive
Hood River, Oregon 97031

WARNING LETTER

Dear Mr. Dominguez:

The Food and Drug Administration (FDA) conducted an inspection of your food processing facility, located at 2885 Van Horn Drive, Hood River, Oregon. The inspection revealed insanitary conditions and deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110. These conditions cause the food products produced in your facility to be adulterated within the meaning of Section 402(a)(4), (copy enclosed) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth. You can find this Act through links in FDA's homepage at www.fda.gov.

At the conclusion of the inspection, you were issued a Form FDA-483 (copy enclosed) which delineated a number of insanitary conditions and GMP deviations present in your facility at the time of the inspection. The insanitary conditions and GMP deviations are as follows:

1. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against contamination of food, including washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the workstation, and at any other time when the hands may have become soiled or contaminated, to comply with 21 CFR 110.10(b)(3). However, your employees failed to wash and sanitize their hands thoroughly after each absence from the workstation or when their hands

may have become soiled or contaminated. Specifically, two employees in the chip packing area left their workstation, handled cardboard boxes and a pallet, returned to their workstation and touched unpackaged finished product with their hands without first washing them.

2. Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food must be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination, to comply with 21 CFR 110.80(b)(7). However, you failed to handle and maintain containers that hold food in a manner that protects against contamination. Specifically, boxes holding chips are stagger stacked so that exposed chips come in direct contact with the exterior bottom of boxes placed on top. Prior to filling, the empty boxes are nested into one another and stored directly on the ground. Also some boxes are used for waste and are indistinguishable from those boxes used in processing.
3. No pests shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests, to comply with 21 CFR 110.35(c). However you failed to take effective measures to exclude pests from the processing and other areas of the facility and protect against the contamination of food on the premises as evidenced by the following.
 - a.) Two birds flew into the bakery area, landed on used baking pans, and ate product residues from the pans.
 - b.) Unpackaged exposed finished tortillas were observed stored on open racks in the processing area approximately ten feet from where birds were active.
 - c.) A large excreta dropping, suspected to be from a male cat that the firm had recently noted in the facility, was observed along the North wall in the storage warehouse.
4. Hand washing devices or fixtures, such as water control valves, must be so designed and constructed to protect against recontamination of clean, sanitized hands, to comply with 21 CFR 110.37(e)(4). However, your hand washing sink in the repack area of the warehouse was not designed and constructed to protect against recontamination of clean, sanitized hands. Specifically, the hand washing sink in the repacking area of the warehouse is plumbed with a garden hose and a garden spigot type of faucet which cannot be easily cleaned. The general condition of this sink does not lend itself to being sanitarily maintained.
5. Hand-washing facilities must be adequate and convenient and be furnished with running water at a suitable temperature, to comply with 21 CFR 110.37(e). However, you failed to provide a hand washing facility with running water at a suitable temperature. Specifically, the hand sink in the repacking area of the warehouse is equipped only with cold water.

6. Equipment and utensils and finished food containers must be maintained in an acceptable condition through appropriate cleaning and sanitizing, to comply with 21 CFR 110.80(b)(1). However, you failed to maintain equipment in an acceptable condition through appropriate cleaning and sanitizing. Specifically, the popcorn popping equipment had product residue on the equipment from previous periods of use, including food residues on the cooler, mixing tank, and mixing drum.
7. You must provide, where necessary, adequate screening or other protection against pests, to comply with 21 CFR 110.20(b)(7). However you failed to provide adequate screening or other protection against pests as evidenced by the following.
 - a.) The North loading door in the warehouse has approximately a two inch gap on the sides and along the floor sufficient to allow pest entry.
 - b.) The South loading bay door is left unscreened and open during the day.
 - c.) The South processing facility door has gaps in the strip curtains that allow bird entry when the doors are open,
8. Your plant building and structures must be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair, to comply with 21 CFR 110.20(b)(4). However, the walls in your facility are not kept in good repair. Specifically, the walls in the warehouse are insulated and covered with small loose fitting boards. The boards are missing and damaged in many spots leaving exposed insulation, which serves as pest harborage areas.

Our inspection has revealed that you have a bird problem in your manufacturing plant that provides a source of contamination to food products and food equipment. The inspection also revealed additional sources of contamination are provided or supported by improper food handling procedures and storage practices; poor employee hand washing practices; lack of adequate hand washing facilities, inadequate equipment cleaning and sanitation, and poor facility repair and construction. It is your responsibility to have an effective, ongoing sanitation program that eliminates the insanitary conditions and sources of food contamination that we have observed.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Luis B. Dominguez, President
Dominguez Family Enterprises, Inc., Hood River, Oregon 97031
Re: Warning Letter SEA 04-16
Page 4

Please respond in writing within fifteen working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Michael J. Donovan, Compliance Officer, at (425) 483-4906.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosures:

Form FDA 483 dated December 9, 2003
21 CFR PART 110
Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act

cc: OSDA with disclosure statement